UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re Rivastigmine Patent Litigation	MDL 1661 (HB)(JCF)
This document relates to:	Civil Action No. 05-CV-2235 (HB)
NOVARTIS PHARMACEUTICALS, CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, and NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.,	
Plaintiffs,	
v.	
SUN PHARMACEUTICAL INDUSTRIES LTD.,	
Defendant.	

SUN PHARMACEUTICAL'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Defendant Sun Pharmaceutical Industries, Limited ("Sun"), by and through its attorneys, answers the Amended Complaint for Patent Infringement of Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, and Novartis International Pharmaceutical Limited ("Novartis" or "Plaintiffs") as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

ANSWER: Sun admits the allegations in Paragraph 1.

PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

ANSWER: Sun admits, on information and belief, the allegations in Paragraph 2.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

ANSWER: Sun admits, on information and belief, the allegations in Paragraph 3.

4. Plaintiff Novartis Pharma AG ("Pharma AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

ANSWER: Sun admits, on information and belief, the allegations in Paragraph 4.

5. Plaintiff Novartis International Pharmaceutical Ltd. ("NIP") is a corporation organized and existing under the laws of Bermuda, having an office and place of business at Hurst Home, 12 Trott Road, Hamilton HM 11, Bermuda.

ANSWER: Sun admits, on information and belief, the allegations in Paragraph 5.

6. On information and belief, SUN is a public limited liability company incorporated and existing under the laws of India and having a principal place of business at Acme Plaza, Andheri Kurla road, Andheri (East) Mumbai 400059, Maharashtra, India.

ANSWER: Sun admits that it is a public limited liability company incorporated and existing under the laws of India, having its principal place of business at Acme Plaza, Andheri Kurla Road, Andheri (East) Mumbai, 400 059, Maharashtra, India.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun admits that this Court has subject matter jurisdiction over

Novartis's infringement claims. Sun denies that Novartis is entitled to any relief pursuant to its Complaint.

8. Sun has consented to personal jurisdiction in this district.

ANSWER: Sun admits that it consented to personal jurisdiction in the U.S. District Court for the Northern District of Illinois for purposes of this case. Sun further admits that it consented to the consolidation of this case for pretrial purposes in the U.S. District Court for the Southern District of New York. Except as expressly admitted, Sun denies the allegations in Paragraph 8.

9. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b).

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Sun admits that venue is proper in this Court for pretrial purposes.

CLAIM FOR RELIEF – PATENT INFRINGEMENT

10. Plaintiff NPC holds an approved new drug application ("NDA") No. 20-823 for Exelon® capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg), which capsules contain the active ingredient rivastigmine tartrate (also known as rivastigmine hydrogen tartrate). Exelon® capsules (1.5 mg, 3 mg, 4.5 mg and 6 mg) were approved by the United States Food and Drug Administration ("FDA") on April 21, 2000, for the treatment of mild to moderate dementia of the Alzheimer's type, and are sold in the United States by Plaintiff NPC.

ANSWER: Sun admits, on information and belief, the allegations in Paragraph 10.

11. The active ingredient in the Exelon® capsules, rivastigmine tartrate, is known chemically as (S)-[N-ethyl-3[(1-dimethylamino)ethyl]-N-methyl-phenyl-carbamate] tartrate and as (S)-N-ethyl-N-methyl-3-[1-(dimethylamino)ethyl]-phenyl carbamate hydrogen-(2R, 3R)-tartrate.

ANSWER: Sun admits, on information and belief, the allegations in Paragraph 11.

12. Novartis AG is the owner of United States Letters Patent No. 5,602,176 ("the '176 patent"). The '176 patent was duly and legally issued on February 11, 1997.

ANSWER: Sun admits that the U.S. Patent Office issued U.S. Patent No. 5,602,176 ("the '176 patent"), entitled "PHENYL CARBAMATE," on February 11, 1997, but specifically denies that the patent was duly or legally issued. Sun further admits that the face of the patent lists Sandoz Ltd., Basel, Switzerland as the assignee. Sun is without knowledge sufficient to form a belief as to the truth or falsity of whether Novartis AG is the owner of the '176 patent. Sun denies the remaining allegations of Paragraph 12.

13. Novartis AG was formed as a result of the merger of Ciba-Geigy AG and Sandoz Ltd., both of Basel, Switzerland. The '176 patent was initially assigned to Sandoz Ltd. on January 29, 1988, which subsequently became Novartis AG after the merger.

ANSWER: Sun admits, on information and belief, that Ciba-Geigy and Sandoz Ltd. merged and formed Novartis AG. Sun also admits that the face of the patent lists Sandoz Ltd., Basel, Switzerland as the assignee. Sun is without knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 13, and therefore denies the same.

14. The '176 patent claims the (S)-[N-ethyl-3-[(1-dimethylamino)ethyl]-N-methyl-phenyl-carbamate] enantiomer substantially free of its (R) isomer, including the tartrate salt thereof, as well as pharmaceutical compositions and methods of treating conditions such as Alzheimer's disease. A true copy of the '176 patent is attached hereto as Exhibit A.

ANSWER: Sun admits that a copy of the '176 patent is attached as Exhibit A and further states that the claims of the patent are set forth in the patent. Sun also admits that the '176 patent relates generally to a phenyl carbamate. Sun denies the remaining allegations of Paragraph 14.

15. On information and belief, Sun submitted to the FDA an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules (hereinafter referred to as "the Sun Rivastigmine Tartrate Products").

ANSWER: Sun admits the allegations in Paragraph 15.

16. On information and belief, Sun submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Sun Rivastigmine Tartrate Products before the expiration of the '176 patent.

ANSWER: Sun admits that it submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of its rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules prior to the expiration of the '176 patent. However, Sun specifically denies any implication that Sun's proposed ANDA product infringes the '176 patent or that the '176 patent is valid and/or enforceable.

17. By filing the ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Sun Rivastigmine Tartrate Products before the expiration of the '176 patent, Sun has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of the Sun Rivastigmine Tartrate Products for which Sun seeks approval in its ANDA will also infringe one or more claims of the '176 patent.

ANSWER: Sun admits that filing an ANDA containing a paragraph IV certification to an Orange-Book-listed patent vests this Court with subject matter jurisdiction pursuant to 35 U.S.C. § 271(e) as to that patent. Sun denies the remaining allegations of Paragraph 17.

18. On information and belief, the Sun Rivastigmine Tartrate Products if approved, will be administered to human patients in a therapeutically effective amount for treatment of mild to moderate dementia of the Alzheimer's type, which administration constitutes direct infringement of the '176 patent. On information and belief, this will occur at Sun's active behest, and with its intent, knowledge and encouragement. On information and belief, Sun will actively induce, encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiff's rights under the '176 patent.

ANSWER: Sun admits that the proposed indication for its ANDA product is for the "treatment of mild to moderate dementia of the Alzheimer's type." Sun denies the remaining allegations of Paragraph 18.

19. On information and belief, Sun made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in its opinion and to the best of its knowledge, the '176 patent is invalid, unenforceable or will not be infringed.

ANSWER: Sun admits that it filed an ANDA containing a paragraph IV certification.

20. On information and belief, Sun's ANDA seeks approval to manufacture and sell the Sun Rivastigmine Tartrate Products, which infringe the '176 patent.

ANSWER: Sun admits that it filed an ANDA seeking approval to manufacture and sell its rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules. Sun denies the remaining allegations of Paragraph 20. Sun specifically denies any allegation that Sun's Proposed ANDA product infringes the '176 patent.

21. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to the Sun Rivastigmine Tartrate Products be a date which is not earlier than February 11, 2014, the expiration date of the '176 patent, and an award of damages for any commercial sale or use of the Sun Rivastigmine Tartrate Products, and any act committed by Sun with respect to the subject matter claimed in the '176 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

ANSWER: Sun denies the allegations in Paragraph 21.

22. On information and belief, when SUN filed its ANDA, it was aware of the '176 patent and that the filing of its ANDA with the request for its approval prior to the expiration of the '176 patent was an act of infringement of this patent.

ANSWER: Sun admits that, when it filed its ANDA seeking approval to manufacture and sell rivastigmine tartrate capsules, it was aware of the existence of the '176 patent. Sun denies the remaining allegations in Paragraph 22.

AFFIRMATIVE DEFENSES

First Affirmative Defense

The manufacture, use, or sale of Sun's product, rivastigmine tartrate 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules, that is the subject of Sun's ANDA No. 77-131 has not infringed, does not infringe, and would not, if marketed, infringe any valid claims of the '176 patent.

Second Affirmative Defense

Claims of the '176 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112 .

Third Affirmative Defense

Claims of the '176 patent are unenforceable based on prosecution laches.

Fourth Affirmative Defense

Any additional defenses or counterclaims that discovery may reveal.

REQUEST FOR RELIEF

WHEREFORE, Defendant Sun Pharmaceutical Industries, Limited respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs.

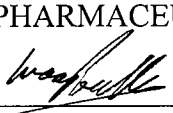
JURY DEMAND

Sun demands trial by jury as to all issues so triable.

Dated: May 23, 2005

Respectfully submitted,

SUN PHARMACEUTICAL INDUSTRIES, LTD.



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CERTIFICATE OF SERVICE

I certify that the foregoing Sun Pharmaceutical's Answer and Affirmative Defenses to Plaintiffs' Amended Complaint for Patent Infringement was served this 23rd day of May, 2005, upon the following counsel via U.S. Mail and via the Court's CM/ECF system:

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One of Sun's Attorneys